REMARKS/ARGUMENTS

Claims 16-18 are pending in this application. Claims 16 and 17 stand rejected and claim 18 has been withdrawn.

Rejection under 35 U.S.C. §102(b)

In the September 20, 2007 Office Action, the Examiner did not mention the previous rejection of claims 16 and 17 under 35 U.S.C. §102(b) as allegedly being anticipated by Xu et al. U.S. Patent No. 6262245. Therefore, Applicants assume that the Examiner has withdrawn this rejection.

Rejection under 35 U.S.C. §102(a)

The Examiner has rejected claims 16 and 17 under 35 U.S.C. §102(a) as allegedly being anticipated by Gish et al. WO 02/30268 (hereinafter "Gish"). For an anticipation rejection under 35 U.S.C. §102 to be proper, a single reference must expressly or inherently disclose each and every element of a claim. In re Paulsen, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); MPEP § 2131 (citing Richardson v. Suzuki Motor Co., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicants traverse the rejection and respectfully submit that Gish fails to disclose all the elements recited in the currently pending claims. Pending claim 16 recites a method comprising the step of "determining that the level of expression of a gene encoding the polypeptide shown as SEQ ID NO:123 in a test sample of prostate tissue cells obtained from said mammal is higher than the expression level in a control sample". The 1170 residue amino acid sequence of SEQ ID NO:123 is shown in Figure 123 and the nucleotide sequence (SEQ ID NO:43) encoding the polypeptide is shown in Figure 43. The Examiner has relied on Gish to make the following assertions in rejecting Applicants currently pending claims.

> Gish et al, disclose a method of diagnosing a prostate cancer by detecting a prostate cancer-associated transcript (mRNA) in a cell from a patient comprising determining a nucleic acid encoding a polypeptide, which is 99.6% identical to the amino acid sequence of SEQ ID NO: 123, different at first 4 amino acids (see sequence search, exhibit B; pages 322-323 and 139, protein sequence, SEQ ID NO:53 having accession no: AA431407 or unigene ID No, Hs.99802, provided in previous office action). [Emphasis added] (page 3 of the February 20, 2007 Final Office Action)

Therefore, the Examiner relies on the nucleotide sequence shown as Gish's SEQ ID NO:53 to conclude that the reference anticipates Applicants' currently pending claims. Contrary to the Examiner's assertions, Applicants respectfully submit that this sequence is not "a gene encoding the polypeptide shown as SEQ ID NO:123" as currently recited in claim 16. The translated 287 residue amino acid sequence of the PBH7 gene (SEQ ID NO:53) is shown on page 323 of Gish as SEQ ID NO:54 and bears no identity to the 1127 amino acid polypeptide currently recited in Applicants' claims. As such, it is not clear how SEQ ID NO:53 of Gish provides any grounds for an anticipation rejection of currently pending claims.

In addition, although the Examiner cites a "sequence search, exhibit B" that accompanied the October 11, 2006 Office Action, this exhibit does not support the Examiner's position. The query sequence of the Examiner's search appears to be an amino acid sequence corresponding to residues 5-1170 of Applicants SEQ ID NO:123 but the alleged database search result appears to correspond to a nucleotides 3-3371 of Gish's nucleic acid sequence shown as SEQ ID NO:105. As such, the Examiner's exhibit B is unrelated to Gish's SEQ ID NO:53 and therefore irrelevant to the asserted 102(a) rejection.

As discussed above, Gish's SEQ ID NO:53 shares no identity with Applicants' SEQ ID NO:123 and therefore Gish does not disclose all the elements of the currently pending claims. Therefore, Gish cannot anticipate currently pending claims 16-17 and Applicants respectfully request the withdrawal of this rejection.

Gish does not contain an enabling disclosure

The Examiner continues to rely on Table 4 on page 139 of the reference in which a gene designated Unigene ID number Hs.98802 is listed as having an R1 value of 33.6. R1 is defined as the "Ratio of tumor to normal body tissue." It is stated in the text immediately above Table 4 that the ratio relates to differential gene expression of Hs.98802 in prostate tumor tissue and normal prostate tissue. However, as discussed above, the gene identified as Hs.98802 does not encode "the polypeptide shown as SEQ ID NO:123" as currently recited in claim 16. Gish's failure to disclose a limitation of the currently pending claims clearly indicates that Gish does not contain the enabling disclosure required for an anticipation rejection. Therefore, Applicants maintain the position previously argued in the July 20, 2007 Response that Gish does not contain

an enabling disclosure and therefore cannot support an anticipation rejection under 35 U.S.C. §102(a).

Rejection under 35 U.S.C. §102(e)

The Examiner has rejected claims 16 and 17 under 35 U.S.C. §102(e) as allegedly being anticipated by Gish et al. US Published App. No. 2007/0014801 (hereinafter "Gish II"). Applicants traverse the rejection and respectfully submit that Gish II fails to teach or suggest all the elements recited in the currently pending claims. The Examiner has relied on Gish II to make the following assertions in rejecting currently pending claims 16-17.

> Gish et al, disclose a method of diagnosing a prostate cancer ... comprising determining a nucleic acid encoding a polypeptide, which is 100% identical to the amino acid sequence of SEQ ID NO: 123 from amino acids 5-1127 (different at first 4 amino acids, see sequence search; SEQ ID NO: 105 having accession no: AI460004[.]... Gish et al., also disclose that expressing the specific prostate cancer gene (SEQ ID NO: 105, PEU5, having accession no: AI460004) in the prostate tumor is up-regulated eight times compared to the normal prostate tissue (Table 3, page 127, line 3). [Emphasis added] (pages 4-5 of the September 20, 2007 Office Action)

Therefore, the Examiner relies on Gish II's disclosure of the PEU5 gene shown as SEQ ID NO:105 as grounds for the anticipation rejection. Again, contrary to the Examiner's assertions Applicants respectfully submit that this sequence is not "a gene encoding the polypeptide shown as SEQ ID NO:123" as currently recited in claim 16.

Applicants respectfully submit that the Examiner's interpretation of what Gish II discloses is erroneous on multiple fronts. First, and most importantly, the nucleotide sequence shown in Gish II as SEQ ID NO: 105 does not encode "the polypeptide shown as SEQ ID NO:123" as recited in currently pending claim 16. The Examiner asserts that the reference discloses a polypeptide that is "100% identical to the amino acid sequence of SEQ ID NO: 123 from amino acids 5-1127", which is itself an erroneous statement as discussed below. However, it does not matter how many amino acid residues of a Gish II polypeptide overlap with SEQ ID NO:123 because the critical fact overlooked by the Examiner is that the reference fails to disclose a nucleotide sequence encoding a polypeptide having the exact 1127 residue amino acid sequence of SEQ ID NO:123 shown in Figure 123. In order to meet the legal requirement for anticipation, the Examiner must establish that Gish II discloses the claim element of "a gene

encoding the polypeptide shown as SEQ ID NO:123" in currently pending claim 16. The Examiner's reference to genes encoding polypeptides that are not identical to Applicants' SEQ ID NO:123 does not meet the legal requirements for anticipation.

Second, the Examiner erroneously states that SEQ ID NO: 105 is "different at [the] first 4 amino acids" when compared to Applicants' SEQ ID NO:123. The translated 1016 residue amino acid sequence of the PEU5 gene (SEQ ID NO:105) is shown on page 340 of Gish II as SEQ ID NO:106. The overlap between SEQ ID NO:106 and Applicants' SEQ ID NO:123 runs from the methionine residue at position 112 to the threonine residue at position 1127. As such, Gish II's SEQ ID NO:106 does not contain all the amino acids shown in SEQ ID NO:123, beginning at the methionine residue at position 1 and ending at the glutamine residue at position 111. Therefore, the difference between SEQ ID NO: 105 of Gish II and Applicants' SEQ ID NO:123 is 111 amino acids and not the 4 amino acids argued by the Examiner.

Third, the Examiner's interpretation of the sequence search of exhibit B is erroneous. As discussed above, the translated polypeptide sequence of SEQ ID NO:105 is the 1016 amino acid sequence shown as SEQ ID NO:106. Despite the fact that Gish II provides the PEU5 polypeptide sequence, the Examiner has inexplicably concluded that the polypeptide includes an additional 111 amino acid residues (methionine 1 to glutamine 111 as discussed above) corresponding to the nucleotides 3-323 of SEQ ID NO:105. However, Gish quite clearly discloses on page 339 of the sequence listing as originally filed that the coding sequence for SEQ ID NO:105 is "324-3374 (underlined sequences correspond to start and stop codons)". In the nucleotide sequence shown as SEQ ID NO:105, an ATG methionine start codon is underlined at nucleotides 324-326 and a TAG stop codon is underlined at nucleotides 3372-3374. Therefore, the Examiner has based the rejection on a non-coding region of the PEU5 gene (SEQ ID NO:105) in Gish II. Applicants respectfully submit that the Examiner's reliance on a non-coding region of the PEU5 gene in Gish II is erroneous and improper. Therefore, the sequence search of exhibit B provided with the October 11, 2006 Office Action does not support the Examiner's position that Gish II discloses "a nucleic acid encoding a polypeptide, which is 100% identical to the amino acid sequence of SEQ ID NO: 123 from amino acids 5-1127 (different at first 4 amino acids[])", as discussed above.

As Gish II does not disclose a nucleic acid encoding Applicants' polypeptide shown as SEQ ID NO:123, it does not disclose all the elements of currently pending claim 16 and

dependent claim 17. Therefore, Gish II cannot anticipate claims 16-17 and Applicants respectfully request the withdrawal of this rejection.

CONCLUSION

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. **08-1641** (referencing Attorney's Docket No. **39766-0225 R1**). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: December 6, 2007

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